

DETAILED ACTION

This Office Action is in response to the amendment filed 12/01/2011. New claims 25-27 have been added. Claim 2 has been canceled.

Applicant's arguments filed 12/01/2011 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 1 and 3-24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Walling (US 6,586,449) in view of Ferno et al. (US 3,845,217) and the rejection is applicable to new claims 25-27.

Applicant argues that Walling discloses that in order to obtain a release rate of 70% within 10 minutes, it is necessary to combine the polyol with the cation exchange resin before admixture with nicotine. Accordingly, one of skill in the art would not have been motivated to combine the cation exchange resin with nicotine before admixture with the polyol as Walling specifically teaches away from such a mixture. Ferno does

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not cure the deficiencies of Walling. There is not teaching or suggestion in Ferno that adding more nicotine to the resin would enhance the rate of nicotine release from the resin. The enhanced nicotine is a function of the polyol. The amount of nicotine in Walling is already at least 50% greater than the amount in the product of Ferno, so there is not motivation as alleged in the Office action to mix the nicotine with the exchange resin.

The Examiner disagrees.

Ferno clearly discloses that the release rate of nicotine from the composition can be varied by varying the amount of nicotine which is bound to a given quantity of cation exchanger. A relatively higher amount of nicotine present gives quicker release (column 3, lines 68-75). Accordingly, the skilled artisan would be motivated to at least try to bind more nicotine to the cation exchange resin of Walling by first mixing it with nicotine, with the expectation that it would produce quicker release of nicotine. The Examiner is not arguing an increase in the amount of nicotine in the composition, but that first mixing the nicotine with the cation exchange resin would increase the amount of nicotine bound to the exchange resin. As cited by MPEP 2144.04, IV, C, the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results.

Applicant presents a corrected affidavit of Carsten Anderson and argues that the skilled artisan would understand the passage from Ferno to mean, when comparing two nicotine resin compositions that differ only in nicotine content, the composition with the

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higher nicotine content will have the faster release. If there are multiple differences between the compositions being compared, then it is not necessarily the case that the composition with the higher nicotine content has the faster release as the other differences between the compositions may also have an impact and outweigh any effect caused by nicotine content. An important difference between the claimed compositions and the compositions of Walling is the strength of the binding between the resin and the nicotine. A weaker bonding, produced by allowing the polyol to bind to the resin before nicotine is introduced, will lead to a faster release, and this is the core teaching of Walling. See for example at claim 1, which refers to the resin "having some of its binding sites partially blocked with polyol" and table 2 where the mixing of a polyol and resin before binding allows for faster release. Therefore one skilled in the art would not have reasonably expected that adding the polyol after mixing the nicotine with resin would be useful for increasing nicotine release rate. Accordingly, one skilled in the art in view of Walling would have reasonably expected that the stronger binding obtained by omitting pretreatment of the resin with the polyol would slow release, whereas Applicant surprisingly and unexpectedly observed the opposite effect.

The Examiner disagrees.

Ferno clearly teaches that the amount of nicotine bound to the exchange resin determines the release of nicotine. The compositions of Walling and the instant invention do not have multiple differences. Both are comprised of nicotine, a polyol, and a cation exchange resin. Based on the disclosure of Ferno, the skilled artisan would expect that the composition with the most nicotine bound to the exchange resin would

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produce the faster release rate. This configuration would reasonably be expected to be produced by mixing nicotine with the resin before addition of polyol. There is no disclosure concerning the relationship between polyol and release, so it would be expected that it would function similarly in both compositions, i.e. augmenting release of nicotine. Walling provides no disclosure concerning the strength of binding between the resin and nicotine. Claim 1 is reasonably interpreted as relating to the amount of available binding sites for nicotine and not to binding strength. Table 2 also does not provide disclosure concerning binding strength. The method suggested by combining Walling and Ferno would similarly produce compositions with some of the binding sites partially blocked by polyol, since addition of nicotine would not be expected to bind to every site on the exchange resin.

Applicant argues the affidavit discusses that the one skilled in the art would understand and consider a difference of 7.6% to be meaningful in practice. Walling also considers such a result as a surprising advantage. In Walling, the nicotine release rate for the sorbitol-containing sample was 7% greater than the nicotine release rate for the sample not containing polyol, and subsequent discussion considers the difference of 7% nicotine to be significant. Runs A and B clearly produce a nicotine delivery product having an average nicotine release rate at least 80%. The average nicotine release rate of the product from the full scale batches was 78.6%. However, 78.6% is within the normal fluctuation of the test method which is ± 2 as disclosed in Walling and the

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average release rates shows that the product having a nicotine release rate of at least 80% is reproducible.

The Examiner disagrees.

As an initial matter, the normal fluctuation discussed by Applicant is in regard to different individual release rates which are added to produce the average release rate, and not between average release rates calculated for different compositions.

Accordingly, since the commercial batches produce an average release rate of 78.6, it is not clear that the instant invention produces the claimed release rate, i.e. at least 80%. Assuming *arguendo* that the normal fluctuation of ± 2 can be applied to different average release rates, the composition of Walling would have a normal fluctuation of average release of 71 ± 2 , i.e. 69 to 73, whereas the full scale commercial batches of the instant invention would have a normal fluctuation of average release of 78.6 ± 2 , i.e. 76.6 to 80.6. Accordingly, when using the normal fluctuation the difference of average release rates between the composition of Walling and the full scale commercial batch of 3.6, i.e. 76.6 versus 73, which has not been established as being statistically significant as to be considered surprising or unexpected. Further, based on the teaching of Ferno, the release rate would reasonably be expected to be enhanced over those of Walling.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is

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(571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612